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May 9, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Dear Sir/Madam:

Re: Docket Nos. 92N-0297 and 88N-0258

- We are a licensed prescription drug wholesaler doing business in 40 states.
- We purchase much of our inventory through several major full-line wholesale distributors.
- We purchase 25% of our inventory through small wholesale distributors who, in some cases, are not authorized distributors for the product they sell.
- We purchase 75% of our inventory from drug companies.
- We do not receive prescription drug pedigrees from full-line wholesalers or from manufacturers. We receive pedigrees from only 4 distributors.
- If we were required to provide prescription drug pedigrees that go back to the manufacturer to our customers, we could do so only in those instances where we have purchased directly from the manufacturer or purchased from an "unauthorized distributor" who is able to provide that complete information to us. However, those "unauthorized distributors" will not be able to do so unless they purchased directly from the manufacturer, which is rarely the case. Since we do most of our business with major full-line wholesalers who do not provide any pedigrees, and because most "unauthorized distributors" will not be able to provide pedigrees back to the manufacturer, we will not be able to lawfully engage in 70% of the transactions we now engage in.
- Our company services over 3000 small distributors, home health agencies, and retail pharmacies.

88N-0258

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- Most of customers do not buy from full line wholesalers because:
 - They do not meet minimum volume requirements
 - Some prescription products are not available from full-line wholesalers
 - Some prescription products are too expensive when purchased from full-line wholesalers
 - Some prescription products are in inconvenient package sizes when purchased from full-line wholesalers
- 90% of our customers have advised us that their business will be adversely affected if we are not able to supply them.
- We have tried to become authorized distributors with at least 6 manufacturers who have turned down our request.
- Out of 180 employees, one-fourth of those persons will be put out of their jobs if the prescription drug requirement becomes effective.
- We support a return to the guidance issued by FDA in August 1988 with respect to prescription drug pedigrees and authorized distributors.

Sincerely Yours,

Shelia Clark

Shelia Clark
Vice President